



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Institutional Review Board (IRB) Records for HHS/OASH Consultation Process

Type of Collection: New

OMB No. OS-0990-New

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a new approval from the Office of Management and Budget of the Office for Human Research Protections (OHRP) requirement that Institutional Review Board records be submitted when an IRB or its institution request an HHS consultation process, for proposed research involving, respectively: (1) pregnant women, human fetuses and neonates; (2) prisoners; or, (3) children, as subjects that are not otherwise approval by an IRB. The Office of the Assistant Secretary for Health, on behalf of the Secretary of HHS, may determine that such research can be conducted or supported by HHS after consulting with experts and allowing for public review of, and comment on, the proposed research.

Likely Respondents: Institutional Review Boards (IRBs)

Annualized Burden Hour Table

45 CFR part 46 - HHS Consultation Process Provision	Number of Respondents	Number of Responses per Respondents	Average Burden per Response	Total Burden Hours
Subpart B, §46. 207	3	1	1	3
Subpart C, §46.306 (iii) and (iv)	3	1	1	3
Subpart D, §46.407	4	1	1	4
Total				10

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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